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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,372	12/21/2001	Roger A. Sabbadini	LPT-3001-UT	3592

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EXAMINER	
GITOMER, RALPH J	
ART UNIT	**PAPER NUMBER**
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/029,372	SABBADINI, ROGER A.	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,15-17,19 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,15-17,19 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment received 2/21/07 has been entered and claims 1-8, 15-17, 19, 21-28 are currently pending in this application. Please inform the examiner of any related cases, abandoned, pending or allowed. And please update the continuing information in the specification where the first page of the specification is incomplete. Priority is granted to 12/22/2000.

The claimed invention appears to be directed to the nexus between the sphinogolipid pathway and any cardiovascular or cerebrovascular disease. All the compounds claimed are known for affecting this pathway and have citations to that effect in the specification. Many of the claimed compounds are well known to be administered to humans for a variety of reasons and any effect derived from such administration would be inherent in the administration..

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8, 15-17, 19, 21 are rejected under 35 U.S.C. 102(a) as being anticipated by each of Gamble and Tabas.

Gamble (6,649,362) entitled "Screening Method for an Agent Having an Effect on a Sphingosine Kinase Signaling Pathway" teaches in column 5 last paragraph bridging to column 6, modulating activity of sphingosine kinase pathway can be by competition with substrates such as sphingosine or ATP, interference with the catalytic activity of sphingosine kinase or interfering with enzyme activation. In column 6 lines 29-36, the pathway includes ceramide, Sph-1-P, protein kinase C. In column 7 lines 27-34, modulation is performed by administering an agent to a mammal the modulates synthesis of components, functions as an antagonist or agonist to components of the pathway. In column 11 last full paragraph, the present invention can be used as a prophylactic or a therapy for conditions such as coronary heart disease. See the claims.

Tabas (6,613,322) entitled "Method for Treating a Subject Suffering from Conditions Associated with an Extracellular Zinc Sphingomyelinase" teaches in column 8 last paragraph conditions treated include atherosclerotic vascular disease, coronary artery disease, and cerebral vascular disease. In column 9 first full paragraph, the inhibitor may be a peptide or polypeptide, a peptidomimetic compound, an organic compound, an nucleic acid, an inorganic compound or an antibody. The inhibitor inactivates zinc sphinogmyelinase.

All the features of the claims are taught by each of the above references for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Gamble and Tabas in view of applicants admissions in the specification.

See the teachings of Gamble and Tabas above

The claims differ from the above references in that they specify the compounds which inhibit the enzymes.

The specification teaches each of the claimed compounds is known to inhibit the respective enzymes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the claimed compounds to modulate the sphingosine pathway to treat vascular disease in view of the primary references because the specification teaches the claimed compounds are known to modulate the sphingosine pathway. The nexus between vascular disease and the sphingosine pathway is clearly described in the primary references above.

Further, some of the claimed compounds such as sodium fluoride, propranolol, and others are known to be administered to humans for various reasons and treating vascular disease would have been inherent in administering the same compounds for any reason.

Applicant's arguments filed 2/21/07 have been fully considered but they are not persuasive.

Applicant argues that the references do not teach treating ischemia or hypoxia as the claims have been amended to read.

It is the examiner's position that Gamble teaches in column 11 last full paragraph, treating coronary heart disease. And Tabas teaches in column 8 last paragraph treating coronary artery disease. Treating ischemia and hypoxia would encompass treating coronary heart disease.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 15-17, 19, 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 1 and all occurrences, "wherein said agent is not an aminoglycoside" is new matter. This concept is not found in the specification as originally filed.

Applicant's arguments filed 2/21/07 have been fully considered but they are not persuasive.

Applicant argues that applicant has the right to claim the material they chose.

It is the examiner's position that the specification as originally filed does not provide any written description for the concept of excluding aminoglycosides.

Claims 1-8, 15-17, 19, 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not reasonably provide enablement for preventing cardiovascular or cerebrovascular disease in a mammal by administering an agent as claimed. No data is presented regarding prevention.

Applicant is silent concerning the above rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 6-8, 15, 16, 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

All dependent claims should begin with a definite article. In claim 5 the preamble is directed to ischemia or hypoxia but the body of the claim is directed to cardiovascular disease. Note this claim is nearly identical to claim 1. In claim 15 it is not seen how cardiovascular tissue may be effected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ralph Gitomer
Primary Examiner
Art Unit 1657